Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks presented herein, is respectfully requested. Claims 2, 4-5, 9, 11 and 14-22 are canceled without prejudice or disclaimer. Thus, the pending claims are claims 1, 3, 6-8, 10 and 12-13.

Objection to Claim 3

The Examiner objected to claim 3, alleging that the term "eye-shaped" recited in the claim is not sufficient to clearly describe a well-known shape. Claim 3, dependent upon claim 1, is directed to a venous cannula, comprising a valveless body having a proximal end sized and adapted for connection to a cardiac bypass system and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient; and a plurality of valveless apertures in the wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures have first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen, and wherein the apertures are arranged into a plurality of rows generally extending along the longitudinal axis of the lumen, wherein the apertures are eye-shaped. Thus, in contrast to the Examiner's assertion that an "eye may take on any number of different shapes," Applicants' submit that the term "eye-shaped" within the context of claim 3 is clear, *i.e.*, "eye-shaped" further describes the opening of an aperture having first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the

longitudinal axis of the lumen. Thus, Applicants' respectfully submit that claim 3 clearly recites that which is considered "eye-shaped." Withdrawal of the objection to claim 3 is therefore respectfully requested.

The 35 U.S.C. § 103(a) rejection of the claims

The Examiner rejected claims 1, 3, 6-8, 10 and 12-13 under 35 U.S.C. §103(a) as being unpatentable over Ash *et al.* (U.S. Patent No. 5,947,953) in view of de la Rama *et al.* (U.S. Patent No. 6,246,914). In particular, the Examiner alleges that it would have been obvious to the art worker to modify the device of Ash *et al.* with the "aperatures shaped in a eye-like fashion" of de la Rama *et al.* "to ensure … fluid … flow though the apertures even when the catheter … buckles" (page 4 of the final Office Action). This rejection is respectfully traversed.

As reiterated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), the framework for the objective analysis of determining obviousness under 35 U.S.C. § 103(a) is stated in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The factual analysis involves (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, and (3) resolving the level of ordinary skill in the pertinent art. Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. Such evidence, often called "secondary considerations," include evidence of commercial success, long-felt but unresolved needs, failure of others, and unexpected results. Cited documents must be considered in their entirety, and it is not permissible to pick and choose from any one document only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such document fairly suggest to one of ordinary skill in the art (*see, e.g., Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 U.S.P.Q. 416 (Fed. Cir. 1986), *cert. denied*, 484 U.S. 823 (1987). MPEP 2141 II.

The claims are directed to a venous cannula, comprising a valveless body having a proximal end sized and adapted for connection to a cardiac bypass system and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient; and a plurality of valveless apertures in the wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures have first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen (claim 1); to such a cannula wherein the apertures are eye-shaped (claim 3); to such a cannula wherein the apertures are arranged into a plurality of rows generally extending along the longitudinal axis of the lumen (claims 6 and 7); and to a venous cannula, comprising a valveless body having a proximal end sized and adapted for connection to a cardiac bypass system and a distal end, the body having a wall defining a lumen extending from the proximal end to the distal end, the lumen having a longitudinal axis; the body being sized and shaped to afford placement of the cannula in a portion of the venous system of a patient; and a plurality of valveless apertures in the wall interconnected with the lumen and permitting fluid flow from outside the lumen into the lumen for transport through the lumen, wherein the apertures include first and second corners defined by arcuate portions that intersect with each other such that the corners do not buckle outwardly as the cannula is flexed (claims 8, 10); and to such a cannula wherein the apertures are arranged into a plurality of rows generally extending along the longitudinal axis of the lumen (claims 12 and 13).

Ash *et al.* disclose a hemodialysis catheter assembly that is split into two separate lumens, each having holes located on its distal end (abstract; column 7, lines 27-29; column 9, lines 62-65; column 11, lines 22-27; FIGs. 5 and 7). The Examiner's attention

is directed to column 7, lines 35-39 of Ash *et al.*, wherein it is disclosed that the lumen, not the holes as asserted by the Examiner at page 4 of the final Office Action, can be configured to have an oval, circular, elliptical, square, triangular or kidney-bean cross-sectional shape (column 7, lines 35-39). However, Ash *et al.* do not disclose or suggest a venous catheter having, *inter alia*, apertures having first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen. Nor do Ash *et al.* disclose or suggest a venous catheter having, *inter alia*, apertures that include first and second corners defined by arcuate portions that intersect with each other such that the corners do not buckle outwardly as the cannula is flexed. Therefore, Ash *et al.* do not render the pending claims obvious.

de la Rama *et al.* do not remedy the deficiencies of Ash *et al.* de la Rama *et al.* disclose a high torque radiofrequency ablation catheter having a slit tubular element with either a plurality of slits, for example, a perpendicular slit, an angled slit, a curved slit, or a random slit, or having at least one continuously spiraling slit (abstract, FIG. 1; column 3, lines 12-19; lines 23-36; column 5, lines 60-61). As defined by de la Rama *et al.*, the "slits" cut into the device are "straight or curved narrow cut[s] or opening[s]" (column 2, lines 65-67). In addition, de la Rama *et al.* disclose covering the slit tubular element within an elastic membrane made from, for example, silicone, latex, polyurethane, thermoplastic elastomer such as Pebax brand polyether block amides, polyethylene balloon, cross-linked polyethylene balloon, permeable membrane, polyethylene terephthalate balloon, and the like (column 6, lines 59-66). As disclosed by de la Rama *et al.*, the slit tubular element may be made from polypropylene, polysulfone, platinum, stainless steel, Nitinol, gold, silver, iridium and/or tungsten (column 6, line 66-column 7, line 3).

However, de la Rama *et al.* do not disclose or suggest a venous catheter, let alone one having, *inter alia*, apertures having first and second corners defined by arcuate

portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is perpendicular to the longitudinal axis of the lumen. Applicants' disclose that the maintenance of proper fluid flow at all times is a desirable feature of venous cannulae (page 2, lines 5-7 in Applicants' specification as filed). de la Rama *et al.*, however, disclose covering the slit tubular element with an elastic membrane. Moreover, given the list of materials disclosed by de la Rama *et al.* to be useful in the manufacture of the slit tubular element, Applicants submit that de la Rama *et al.* clearly do not disclose or suggest apertures that include first and second corners defined by arcuate portions that intersect with each other such that the corners do not buckle outwardly as the cannula is flexed. Therefore, de la Rama *et al.*, either alone or in combination with Ash *et al.* , do not render the pending claims obvious.

Applicants' respectfully submit that *prima facie* obviousness has not been established. As discussed above, neither Ash *et al.* nor de la Rama *et al.* disclose or suggest all of the limitations of the pending claims. The Examiner concedes at page 3 of the final Office Action that Ash *et al.* do not disclose the claimed aperture. In contrast to the Examiner's assertion regarding FIG. 3 of de la Rama *et al.* at page 3 of the final Office Action, Applicants' respectfully submit that de la Rama *et al.* do not disclose or suggest a plurality of apertures taking on an eye-shape. The Examiner is urged to consider that any disclosure in FIG. 3 is limited to the disposition of de la Rama *et al.*'s so-called slits, *i.e.*, "straight or curved narrow cut[s] or opening[s]," *when the ablation catheter is flexed* ("at a bending state") (column 2, lines 65-67; column 6, lines 10-17). As evidence that de la Rama *et al.*'s slits are not designed to retain the shape shown in FIG. 3, the Examiner's attention is directed to FIG. 4 of de la Rama *et al.*, which discloses the disposition of the slits while in a non-bending state. As can be seen, slit 13 of the device is neither eye-shaped nor open.

Even assuming, *arguendo*, that de la Rama *et al.* disclose a catheter having an eye-shaped aperture, which they do not, Applicants' are unable to locate in de la Rama *et*

al. any disclosure or suggestion that the slits are designed to open when the device is not flexed. Moreover, both Ash *et al.* and de la Rama *et al.* are silent as to whether the holes or slits of their respective devices buckle outwardly as the device is flexed. Applicants submit that if slits were located on the *concave* side of the curved catheter shown in FIG. 3 of de la Rama *et al.*, *i.e.*, directly opposed to the slits shown in FIG. 3, they would buckle outwardly given that the disclosed list of materials used to manufacture the slit tubular element of the de la Rama *et al.* device are disclosed to confer torque transmissibility to the de la Rama *et al.* catheter. Thus, Applicants' submit that in contrast to the Examiner's assertion at page 4 of the final Office Action, de la Rama *et al.* do not disclose or suggest that their catheter ensures fluid flow though apertures when buckled.

Applicants' respectfully submit that the art worker would not be motivated to modify the holes of Ash *et al.* with the slits of de la Rama *et al.* as suggested by the Examiner, and would not have a reasonable expectation that such catheter would be successful for perfusion. The Examiner is respectfully requested to consider that such a modification would render the Ash *et al.* catheter unsatisfactory for its intended purpose, *i.e.*, replacing the holes at the distal end of the Ash *et al.* catheter with the slits of de la Rama *et al.* would limit the efficacy of the hemodialysis catheter depending upon its state of flex, *i.e.*, the catheter slits would open (or not) during a dialysis procedure depending upon the bending state of the catheter, and/or potentially pinch sensitive tissue in the slits while flexed causing injury to the patient. See M.P.E.P. 2143.01(V).

Furthermore, given the disclosure by de la Rama *et al.* to include perpendicular slits, angled slits, curved slits, and/or random slits in the ablation catheter actually *teaches away* from apertures having any particular shape, let alone apertures having "first and second corners defined by arcuate portions that intersect with each other, wherein each of the apertures has a longer major axis and a shorter minor axis with the first and second corners along the longer major axis, and wherein the longer major axis is

perpendicular to the longitudinal axis of the lumen" or the "eye-shaped" apertures as presently claimed.

Therefore, for the reasons discussed above, it is respectfully submitted that the pending claims are not *prima facie* obvious over Ash *et al.* in view of de la Rama *et al.* Withdrawal of the 35 U.S.C. §103(a) rejection of the claims is thus proper and respectfully requested.

Claims 6-7 and 12-13 are independently patentable

As discussed above, neither Ash *et al.* nor de la Rama *et al.* disclose or suggest Applicants' cannula as claimed. As discussed above, Ash *et al.* disclose that the location of the hemodialysis catheter holes is limited to the distal end of the device. In particular, Ash *et al.* disclose that the holes are arranged "helically and circumferentially around the distal end regions" of the device (column 11, lines 29-34). de la Rama *et al.*, as discussed above, disclose that their ablation catheter may have either one continuous spiral slit (see FIGs. 6-7) or a plurality of slits (FIGs. 2-5). Regarding the location of the latter, de la Rama *et al.* disclose that the plurality of slits may be on the "same side, on the opposite side, or randomly on the surface of the split tubular element" (column 6, lines 5-7). Given the foregoing, it is respectfully submitted that both Ash *et al.* and de la Rama *et al.* actually *teach away* from apertures that are "arranged into a plurality of rows generally extending along the longitudinal axis of the lumen" and apertures that are "evenly distributed on the body . . . offset such that the apertures in the adjacent rows are different distances from a distal tip of the body" as claimed in the present invention. Thus, it is respectfully submitted that claims 6-7 and 12-13 are patentable over the cited art, and notice of their allowance is respectfully requested.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is respectfully requested. The Examiner is invited to telephone Applicants' Representative at 763-505-8423 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-2546.

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